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Proposed Registration Decision PRD2011-17

Copper, present as Basic Copper Carbonate

(publié aussi en français)

19 September 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2011-17E (print version)
H113-9/2011-17E-PDF (PDF version)

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Overview

Proposed Registration Decision for Copper, present as Basic Copper Carbonate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Basic Copper Carbonate and MicroPro 200C-TS, containing the technical grade active ingredient copper, present as basic copper carbonate, for treating wood for above-ground, ground contact and fresh water contact uses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Basic Copper Carbonate and MicroPro 200C-TS.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on copper, present as basic copper carbonate, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on copper, present as basic copper carbonate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Copper, present as Basic Copper Carbonate?

Basic copper carbonate is a new, copper-based active ingredient for use in combination with other active ingredients, as a wood preservative. It must be combined with Carboquat, to form an ACQ-type of wood preservative. Basic copper carbonate differs from currently registered ACQ wood preservatives in that the copper is not dissolved but is in a solid form.

Health Considerations

Can Approved Uses of Copper, Present as Basic Copper Carbonate, Affect Human Health?

Copper, present as basic copper carbonate, is unlikely to affect your health when used according to label directions.

Potential exposure to copper, present as basic copper carbonate, may occur when handling and applying the product, or coming into contact with treated wood surfaces. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

In laboratory animals, copper, present as basic copper carbonate, was of slight acute toxicity via the oral and inhalation routes of exposure, and therefore the words "Caution – Poison" are required on the principle display panel of the label. It was of low toxicity following a single dermal exposure. Copper, present as basic copper carbonate, was minimally irritating to the eyes, not irritating to the skin, and did not cause an allergic skin reaction.

The end-use product MicroPro200C-TS was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and slightly irritating to the skin, and did not cause an allergic skin reaction.

The active component of toxicological concern with the majority of copper-containing pesticides is the copper ion, and most copper compounds, including basic copper carbonate, can therefore be considered similar in terms of their toxicity. Copper is a naturally occurring metal that occurs in many foods including organ meats, seafood, beans, nuts and whole grains, and in drinking water. Copper is also an essential element in maintaining normal health in humans, with adverse effects more likely to result from copper deficiency rather than excess. Humans have efficient mechanisms in place to regulate levels of copper in the body, and as such are generally protected from exposure to excess levels of copper.

Residues in Food

As MicroPro 200C-TS is not proposed for use on food, a food residue assessment was not required.

Occupational Risks From Handling MicroPro 200C-TS

Occupational risks are not of concern when MicroPro 200C-TS is used according to the proposed label directions, which include protective measures.

Workers can come in direct contact with MicroPro 200C-TS while treating wood in commercial wood treatment facilities as well as while handling treated wood. Therefore, the label specifies that workers wear full-face protection, chemical-resistant coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear when handling the concentrate or dilute solution, when opening treating cylinder doors and during cleaning, maintenance and repair activities on storage vessels or treating cylinders, and wear chemical-resistant coveralls over long sleeved shirt and long pants, goggles or face shield and chemical-resistant gloves when handling freshly treated wood. In addition, a closed system must be used when mixing/loading MicroPro 200C-TS. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for workers, risk to these individuals are not a concern.

Environmental Considerations

What Happens When Copper, Present as Basic Copper Carbonate, Is Introduced Into the Environment?

Copper, present as basic copper carbonate is toxic to aquatic organisms and terrestrial plants, therefore, risk-reduction measures must be observed.

Copper, present as basic copper carbonate is an inorganic form of copper. Copper is an element that occurs naturally in the environment and does not break down any further via hydrolysis, metabolism or any other degradation processes. The free cupric ion has a high sorption affinity for soil, sediments and organic matter, and copper applied to the soil surface is not expected to move readily into groundwater. The copper ion is highly reactive, especially in aquatic environments. The form in which copper is found depends on the pH of the medium and the nature and concentration of other forms of copper present.

Copper is expected to pose a risk to aquatic organisms and terrestrial vascular plants. As such, mitigative measures must be taken to minimise adverse effects on plant populations and aquatic organisms. Risk is mitigated by precautionary label statements limiting exposure of aquatic systems to copper.

Value Considerations

What is the value of the end-use product MicroPro 200C-TS?

MicroPro 200C-TS is a particulate copper source that must be added to Carboquat to form heavy duty wood preservatives for pressure treating lumber for above-ground, ground contact, and fresh water applications such as fence posts and boards, decks, docks, walkways and wood shingles.

In combination with Carboquat, MicroPro 200C-TS imparts to the treated wood an effective protection against decay fungi, extending the usable life of the wood. Wood treated with MicroPro 200C-TS is intended for above-ground, ground contact and fresh water contact uses. While similar to currently registered ACQ wood preservatives, the copper source of MicroPro 200C-TS is in a solid, particulate, "micronized" form rather than a dissolved form. This allows MicroPro 200C-TS to be dispersed in water rather than dissolving the copper in ammonia or ethanolamine. Due to the small size of the copper particles, MicroPro 200C-TS is able to penetrate wood species with reduced leaching relative to dissolved copper.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of MicroPro 200C-TS to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with MicroPro 200C-TS on the skin or through inhalation of spray mists, workers must wear full-face protection, chemical-resistant coveralls over long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear when handling the concentrate or dilute solution, when opening treating cylinder doors and during cleaning, maintenance and repair activities on storage vessels or treating cylinders, and wear chemical-resistant coveralls over long sleeved shirt and long pants, goggles or face shield and chemical-resistant gloves when handling freshly treated wood. In addition, a closed system must be used when mixing/loading MicroPro 200C-TS.

Environment

Copper is expected to pose a risk to aquatic organisms and terrestrial vascular plants. As such, mitigative measures must be taken to minimise adverse effects on plant populations and aquatic organisms. Risk is mitigated by precautionary label statements limiting exposure of aquatic systems to copper.

Next Steps

Before making a final registration decision on copper, present as basic copper carbonate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

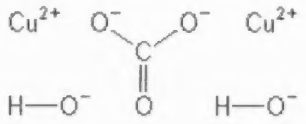
When the PMRA makes its registration decision, it will publish a Registration Decision on copper, present as basic copper carbonate (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Copper, present as Basic Copper Carbonate

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Copper, present as basic copper carbonate
Function	Heavy duty wood preservative
Chemical name	Copper carbonate, basic
1. International Union of Pure and Applied Chemistry (IUPAC)	Not available
2. Chemical Abstracts Service (CAS)	[μ-[carbonato(2−)-κ*O*:κ*O'*]]dihydroxydicopper
CAS number	12069-69-1
Molecular formula	$CH_2Cu_2O_5$
Molecular weight	221.1
Structural formula	
Purity of the active ingredient	95.1 % nominal (basic copper carbonate) 54.6 % nominal (copper, present as basic copper carbonate)

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—Basic Copper Carbonate

Property	Result
Colour and physical state	Blue-green
Odour	Odourless
Melting range	Decomposed at 200°C before melting point could be observed
Boiling point or range	N/A the product is a solid
Density	1.474 g/mL (pour density) 1.895 g/mL (tap density)
Vapour pressure at 25°C	5×10^{-5} Pa
Ultraviolet (UV)-visible spectrum	$\lambda_{max} = 205$ ($\varepsilon_{205} = 2964.8$ $M^{-1}cm^{-1}$) for pH 1.5. Higher pH (6 or 12) did not show any absorbance from 200 – 750 nm.
Solubility in water at 30°C	$< 2.5 \times 10^{-4}$ g/L
Solubility in organic solvents at 20°C (g/100 mL)	Not determined, since the product is only to be used in aqueous formulations
n-Octanol-water partition coefficient (K_{ow})	N/A. The substance is an inorganic salt that is unlikely to be soluble in octanol.
Dissociation constant (pK_a)	N/A. The substance is an inorganic salt that has no dissociable groups.
Stability (temperature, metal)	The active ingredient concentration was stable to metals and metal ions for 14 days at ambient temperature and 54°C, stored in HDPE centrifuge tubes. May be stored in carbon steel or polypropylene, but not aluminum containers.

End-Use Product—MicroPro 200C-TS

Property	Result
Colour	Light green
Odour	Latex paint-like odour
Physical state	Liquid
Formulation type	Solution
Guarantee	28.0% copper, present as basic copper carbonate
Container material and description	HDPE bulk tote containers
Density	1.6527 at 25°C (relative density)
pH of 1% dispersion in water	8.81
Oxidizing or reducing action	No chemical incompatibility with the fire extinguishing agents, water and ammonium phosphate monobasic solution or with iron powder or kerosene. Oxidized by potassium permanganate, thus the product may not be compatible with other strong oxidizing agents.
Storage stability	Product was found to be stable after one year of storage under ambient conditions, in HDPE bottles.
Corrosion characteristics	Product was found not to be corrosive after one year of storage under ambient conditions, in HDPE bottles.
Explodability	Product is not expected to be explosive.

1.3 Directions for Use

The treated wood is for fresh water, ground contact and above ground contact uses, but cannot be used for critical infrastructures such as utility poles. The treated wood is intended for applications such as fence posts and boards, decks, docks, walkways and wood shingles. The relevant parameters for treatment are outlined in Table 1.3.1.

Table 1.3.1 Wood treatment rates for MicroPro 200C-TS added to Carboquat (MCQ)

Combination	Treatment solution (% a.i.)	Wood Exposure	Target Retention rate (kg/m^3)
MCQ (MicroPro 200C-TS + Carboquat at 2 :1 ratio)	0.5–3.4	Above Ground	4.0
		Ground & Fresh water Contact	6.4

1.4 Mode of Action

Copper has a well established efficacy against decay fungi resulting in the non-specific denaturation of proteins and enzymes. The wood preservatives formed by adding MicroPro 200C-TS to Carboquat is similar to the currently registered ACQ preservatives, with the major difference being that the copper active is in solid form rather than in solution. The biocidal efficacy and ability of the soluble copper ion to penetrate wood has been well established, and it appears as though the micronized copper particles are also capable of sufficiently penetrating the wood and once in the acidic medium of the wood are dissolved at a slow rate that is sufficient to prevent fungi from decaying the wood.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in copper, present as basic copper carbonate, have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Standard analytical methods for analysis of copper are publicly available, and include flame ionizing atomic absorption spectroscopy (Flame-AAS), atomic emission spectroscopy (AES), and inductively coupled plasma (ICP) with mass spectrometric (MS), or AES detection. These methods can be applied to plant and animal matrices and environmental media.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Certain copper-containing pesticides were recently re-evaluated by the PMRA (PRVD2009-04/RVD 2010-05). The re-evaluation was based largely upon the conclusions reached in the USEPA Reregistration Eligibility Decision (RED) for Coppers, published in July 2006, and updated in 2009. Although basic copper carbonate was not registered in Canada at the time, it was included in the cluster of copper compounds which were addressed in the USEPA RED. The active component of toxicological concern with the majority of copper-containing pesticides is elemental copper (the cupric ion), and most copper compounds, including basic copper carbonate, can be considered similar in terms of their toxicity.

These recent re-evaluations were used as the basis for the current assessment. With the exception of the acute toxicity studies, which were conducted on copper, present as basic copper carbonate, and the end-use product MicroPro200C-TS, the remainder of the toxicology discussion will refer to copper when present as the copper ion.

Copper is a naturally occurring metal that occurs in many foods and in drinking water. Copper is also an essential element, with adverse effects in humans more likely to result from copper deficiency rather than excess.

Technical grade copper, present as basic copper carbonate, was of slight acute toxicity via the oral and inhalation routes of exposure and of low acute toxicity following dermal exposure in rats. It was minimally irritating to the eyes and not irritating to the skin of rabbits. Copper, present as basic copper carbonate, was not a dermal sensitizer when tested using the Buehler method in guinea pigs. The end-use product, MicroPro 200C-TS, was considered to be of low acute toxicity in rats via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eyes and slightly irritating to the skin of rabbits, and was not considered to be a dermal sensitizer.

Dietary exposure of laboratory animals to high levels of copper was associated with decreased food intake and body weight gains, irritation of the stomach, and increased copper concentrations in the liver. High levels of copper in the drinking water of mice suggested an effect on the immune system, a finding which has also been reported for other trace metals.

There was no evidence of copper being carcinogenic or resulting in any other systemic toxicity in animals having normal copper homoeostasis. Available studies in animals generally indicate that the main concern for reproductive and developmental effects is associated with copper deficiency rather than excess.

Humans have efficient mechanisms in place to regulate levels of copper in the body, and as such are generally protected from exposure to excess levels of copper; however, some less common genetic conditions in humans may cause abnormal copper metabolism.

Based on the exposure considerations (Section 3.4), and consistent with the approach taken by the USEPA, upon which the recent PMRA re-evaluation of copper pesticides was based, toxicological endpoints were not established for the proposed use as a heavy-duty wood preservative. Therefore, a qualitative risk assessment was conducted.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada and the United States were searched and reviewed for basic copper carbonate. As of July 29, 2011, there were no incident reports submitted for products containing basic copper carbonate.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

A qualitative approach to the human health risk assessment was taken for copper, present as basic copper carbonate. Available information does not indicate that the young would be more sensitive to basic copper carbonate toxicity than the adult; consequently, there was no residual concern relating to risks to infants and children.

3.2 Acute Reference Dose (ARfD) and Acceptable Daily Intake (ADI)

With respect to the proposed use, establishment of an Acute Reference Dose and Acceptable Daily Intake was not required since there are no proposed food uses.

Cancer Assessment
There was no evidence to suggest that copper has carcinogenic potential; therefore, no cancer risk assessment was necessary.

3.3 Occupational and Residential Risk Assessment

3.3.1 Toxicological Endpoints

Toxicology endpoints were not established for the currently proposed use as a heavy-duty wood preservative.

Aggregate Exposure
Aggregate exposure to copper, present as basic copper carbonate, in residential settings would consist of background levels found in food and drinking water, in addition to potential oral and dermal exposure to copper from contact with treated wood. However, because oral and dermal exposure from contact with treated wood is considered to be minimal, no further aggregation has been performed.

3.3.2 Occupational Exposure and Risk

The treatment solution concentrations for copper, present as basic copper carbonate, fit within the registered values. No systemic toxicological endpoints of concern were identified for dermal exposures to copper, present as basic copper carbonate, and no dermal, oral or inhalation endpoints of toxicological concern were established. As such, a quantitative chemical handler risk assessment is not required for MicroPro 200C-TS.

3.4 Food Residues Exposure Assessment

As MicroPro 200C-TS is not proposed for use on food, a food residue assessment was not required.

4.0 Impact on the Environment

A laboratory study on the leaching of copper from treated wood was submitted to support the registration of the end-use product, MicroPro 200C-TS. When comparing specific uses, target retention rates and expected leaching rates to those for the registered uses of copper, no additional environmental risk is expected from the use of this product. Therefore, a new environmental assessment was not required. A complete evaluation of copper's environmental fate and toxicity is available in Proposed Re-evaluation Decision PRVD2009-04, *Copper Pesticides*. Environmental concerns are mitigated on the label.

5.0 Value

5.1 Effectiveness Against Pests

Data from two laboratory soil-block studies, two ground-contact soil bed trials, and seven ground-contact field trials were submitted. The studies were found to have appropriate experimental designs and to consist of a large enough number of test rates to establish target retentions. The efficacy of the MCQ preservative was evaluated as weight loss due to decay in the soil block tests, and by visual observation of the wood condition in the soil bed, and field trials. These visual observations were made on an annual basis and recorded in a semi-quantitative manner. No commercial Canadian wood species were included in the trials, but two detailed wood treatability studies were provided that clearly demonstrated that the retention rates found to be effective in the field trials were able to be achieved in many Canadian wood species within the recommended treatment parameters.

5.1.1 Acceptable Efficacy Claims

The submitted data established an effective range of retention rates that are presented in Table 5.1.1. The range of rates was determined by testing treatments of a variety of non-Canadian wood species in field tests at various locations within the United States and Australia.

Table 5.1.1 Wood treatment rates for MicroPro 200C-TS added to Carboquat (MCQ) as supported by data

Combination	Treatment solution (%)	Wood Exposure	Target Retention rate (kg/m^3)
MCQ (MicroPro 200C-TS + Carboquat at 2 :1 ratio)	0.5–3.4	Above Ground	4.0
		Ground & Fresh water Contact	6.4

5.2 Economics

No information provided.

5.3 Sustainability

5.3.1 Survey of Alternatives

The availability of copper, present as basic copper carbonate, would provide an additional source and physical form of copper to one of the two main wood preservative chemistries registered for residential uses. In addition, the micronized, dispersed copper provides improvements to the MCQ wood preservatives over the traditional ACQ in that they are dispersed in water, rather than dissolved in organic solvents, and have a lower copper leaching rate. The use of naturally durable wood such as western red cedar is an alternative to treated wood for residential applications, but its use and resistance to decay are limited.

The key options available for treatment of wood for residential uses are summarized in Appendix I, Table 3.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Basic copper carbonate offers a new form of the active ingredient copper for wood preservation. The end-use product, MicroPro 200C-TS, should be compatible with pressure treatment plants currently set up to treat with ACQ-type preservatives, but may require modifications to treatment cylinders that are set up to treat with CCA.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Copper-resistant fungi such as *Postia placenta* have been known to be problematic with wood preservative efficacy. However, the copper in MicroPro 200C-TS is not for use alone, but will be mixed with a quaternary ammonium compound (i.e. Carboquat) to form MCQ. It is unlikely that resistance will form to this combination of active ingredients as the secondary biocide will kill the copper resistant fungi, while fungi that may be resistant to the secondary biocides will be susceptible to the copper. Laboratory soil block studies that included copper-tolerant decay fungi have been provided, and it can also be assumed that copper tolerant fungi would have been present in at least some of the submitted long-term field studies, all of which demonstrated acceptable efficacy. Furthermore, this MCQ preservative is not expected to differ substantially from conventional ACQ preservatives which have been on the market for many years with no significant resistance issues being reported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal TSMP, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal TSMP and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of pesticides containing copper. The PMRA has reached the following conclusions.

- Copper does not bioaccumulate. The n-octanol–water partition coefficient (log Kow) is not applicable as copper is not soluble in water and octanol. The TSMP Track 1 cut-off criterion is ≥5.0. Copper is persistent, but binds to soil particles and becomes biologically unavailable. Aerobic soil half-life is far above the TSMP Track 1 criterion of 182 days; therefore, copper is not a candidate for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.1), the technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical products of copper.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

7.0 Summary

7.1 Human Health and Safety

Copper is a naturally occurring metal that is present in water and air, and occurs naturally in various foods, including organ meats, seafood, beans, nuts and whole grains. Copper is an essential element in maintaining normal health in humans, and subsequently, adverse effects are more likely due to copper deficiency rather than excess. In addition, humans have efficient homeostatic mechanisms in place to regulate total body burden of copper. It is unlikely that exposure to copper, present as basic copper carbonate, as a result of the proposed use pattern would result in systemic toxicity.Workers treating wood with MicroPro 200C-TS and workers handling treated wood are not expected to be exposed to levels of MicroPro 200C-TS that will result in an unacceptable risk when MicroPro 200C-TS is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Residential exposure to individuals contacting treated wood is not expected to result in unacceptable risk when MicroPro 200C-TS is used according to label directions.

As MicroPro 200C-TS is not proposed for use on food, a food residue assessment was not required.

7.2 Environmental Risk

Copper, present as basic copper carbonate, is an inorganic form of copper. Copper is an element that occurs naturally in the environment and does not break down any further via hydrolysis, metabolism or any other degradation processes. The free cupric ion has a high sorption affinity for soil, sediments and organic matter, and copper applied to the soil surface is not expected to move readily into groundwater.

Copper is expected to pose a risk to aquatic organisms and terrestrial vascular plants. As such, mitigative measures must be taken to minimise adverse effects on plant populations and aquatic organisms. Risk is mitigated by precautionary label statements limiting exposure of aquatic systems to copper.

7.3 Value

The data submitted to register MicroPro 200C-TS are adequate to demonstrate its efficacy for use as a heavy-duty wood preservative for the treatment of lumber intended for above-ground, ground contact and fresh water uses. The active ingredient copper, present as basic copper carbonate, offers advantages over the current soluble copper actives used in the currently registered ACQ wood preservatives in that it is dispersed in water with no need for organic solvents. Data have also been provided showing that the micronized copper leaches less from the MCQ and MCA preservatives than the conventional ACQ and CA preservatives.

7.4 Unsupported Uses

There are no unsupported uses proposed on the label.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Basic Copper Carbonate and MicroPro 200C-TS, containing the technical grade active ingredient copper, present as basic copper carbonate, for treating wood for above-ground, ground contact and fresh water contact uses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

a.i.	active ingredient
ACQ	Ammoniacal Copper Quaternary, a class of wood preservative based on the actives copper and a quaternary ammonium compound
ADI	acceptable daily intake
AES	atomic emission spectroscopy
ARfD	acute reference dose
bw	body weight
CA	copper azole-type wood preservative
CAS	Chemical Abstracts Service
CCA	chromated copper arsenate
cm	centimetres
	Flame-AAS flame ionizing atomic absorption spectroscopy
g	gram
HDPE	high density polyethylene (plastic)
ICP	inductively coupled plasma
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
m	metre(s)
MAS	maximum average score for 24, 48 and 72 hours
MCA	An copper azole-type of wood preservative in which the copper active is in a "micronized" particulate form that is dispersed in water, rather than dissolved in organic solvents.
MCQ	An ACQ-type of wood preservative in which the copper active is in a "micronized" particulate form that is dispersed in water, rather than dissolved in organic solvents.
mg	milligram
MIS	maximum irritation score
mL	millilitre
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
nm	nanometres
Pa	pascals
PCPA	*Pest Control Product Act*
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Acute Toxicity Profile of MicroPro 200C-TS (48% copper carbonate)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Up and Down Procedure Sprague Dawley rats PMRA #1730512	LD_{50} > 2000 mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA #1730513	LD_{50} > 2000 mg/kg bw Low toxicity
Acute inhalation toxicity (nose-only) Sprague Dawley rats PMRA #1730514	LC_{50} > 2.06 mg/L Low toxicity
Dermal irritation NZW rabbits PMRA #1730515	MAS = 0.67 MIS = 8 at 1 hour Minimally irritating
Eye irritation NZW rabbits PMRA #1730516	MAS = 0 MIS = 0.7 at 1 hour Non-irritating
Dermal sensitization (Buehler test) Hartley guinea pigs PMRA #1730517	Non-sensitizer

Table 2 Acute Toxicity Profile of Technical Basic Copper Carbonate

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Sprague Dawley rats PMRA #1676681	LD_{50} ♂ =1889 mg/kg bw ♀ < 5000mg/kg bw Slightly toxic
Acute dermal toxicity Sprague Dawley rats PMRA #1676682	LD_{50} > 5000mg/kg bw Low toxicity
Acute Inhalation Sprague Dawley rats PMRA #1676683	LC_{50} is between 0.54 and 2.05 mg/L Slightly toxic
Primary Eye Irritation NZW rabbits PMRA #1676684	MAS = 1 MIS = 3 at 24 hours Minimally irritating
Primary Skin Irritation NZW rabbits PMRA #1676685	MAS = 0 MIS = 0.7 at 1 hour Non-irritating
Skin Sensitization Buehler Hartley guinea pigs PMRA 1676686	Non-sensitizer

Table 3 Alternative Wood Preservatives For The Treatment Of Wood For Residential Uses

End-Use Product	PCP#	Actives	Registered Uses
ACQ 2102	27130	COPPER ETHANOLAMINE COMPLEXES; N-ALKYL (67% C12, 25% C14, 7% C16, 1% C18) DIMETHYL BENZYL AMMONIUM CHLORIDE	Non-Industrial Wood; Above-Ground Ground Contact
NW 100	27131	CUPROUS OXIDE; N-ALKYL (67% C12, 25% C14, 7% C16, 1% C18) DIMETHYL BENZYL AMMONIUM CHLORIDE	Non-Industrial Wood; Above-Ground Ground Contact
Wolman NB	27132	CUPROUS OXIDE; TEBUCONAZOLE	Non-Industrial Wood; Above-Ground Ground Contact Fresh Water Contact

Table 4 Use (Label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Proposed label claim	Supported use claim
Use Limitations *For use in the treatment of wood products for above ground, ground contact and water contact uses such as lumber, timbers, landscape ties, fence boards, and posts, building poles and decks, docks, waterways, and wood shingles.*	***Use Limitations*** *For use in the treatment of wood products for above ground, ground contact and fresh water contact uses such as lumber, timbers, landscape ties, fence boards, and posts, building poles and decks, docks, waterways, and wood shingles.* *Do not use to treat wood used in critical infrastructures such as bridges, utility poles, pilings, etc.*
Directions for Use *MicroPro 200C-TS is an end-use product for use in closed vacuum-pressure treatment systems for wood products. MicroPro 200C-TS must be tank mixed with either Carboquat WP-50 (PCP # 28633) or MTZ (PCP # XXXXX). When mixing MicroPro 200C-TS with Carboquat WP-50, prepare a treatment solution of 0.75% to 5.0% active by mixing MicroPro 200C-TS and Carboquat WP-50 at a 2:1 ratio, with water. When mixing MicroPro 200C-TS with MTZ, prepare treatment solution strength of 0.5% to 3.0% active by mixing MicroPro 200C-TS and MTZ at a 25:1 ratio, with water.* *TARGET RETENTION RATES* *MicroPro 200C-TS + Carboquat* *Above ground, non structural 2.0 kg/m^3* *Above ground, structural 4.0 kg/m^3* *Ground & Freshwater contact 6.4 kg/m^3* *MicroPro 200C-TS + MTZ* *Above ground, non structural 0.9 kg/m^3* *Above ground, structural 1.7 kg/m^3* *Ground & Freshwater contact 3.3 kg/m^3*	***Directions for Use*** *MicroPro 200C-TS is an end-use product for use in closed vacuum-pressure treatment systems for wood products. MicroPro 200C-TS must be tank mixed with Carboquat WP-50 (PCP # 28633). When mixing MicroPro 200C-TS with Carboquat WP-50, prepare a treatment solution of 0.5% to 3.4% active by mixing MicroPro 200C-TS and Carboquat WP-50 at a 2:1 ratio, with water.* *TARGET RETENTION RATES* *MicroPro 200C-TS + Carboquat* *Above ground, non structural 4.0 kg/m^3* *Above ground, structural 4.0 kg/m^3* *Ground & Freshwater contact 6.4 kg/m^3*

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1676675	2008, DACO Summary Document, DACO: 2.0,2.1,2.2,2.3,2.4,2.5, 2.6,2.7,2.8,2.9 CBI
1676676	2006, Basic Copper Carbonate Product Chemistry Data, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1 CBI
1676677	2006, Preliminary Analysis of Basic Copper Carbonate, DACO: 2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1676678	2006, Physical and Chemical Characteristics of Basic Copper Carbonate, DACO: 2.14,2.14.1,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,8.2.1 CBI
1676679	2006, Basic Copper Carbonate Vapour Pressure, DACO: 2.14.9,8.2.1
1728359	2009, DACO 2.2, DACO: 2.2 CBI
1728360	2009, Basic Copper Carbonate Label, DACO: 1.1.1
1730058	2009, Basic Copper Carbonate Label, DACO: 1.1.1 (screened)
1858859	United States Department of the Interior, 1998, Guidelines for Interpretation of the Biological Effects of Selected Constituents in Biota, Water, and Sediment - Copper, DACO: 9.6.2.5
1872714	2010, Ruanshi - DACO 2 Product Chemistry, DACO: 2.11.2,2.11.3 CBI
1872714	2010, Ruanshi - DACO 2 Product Chemistry, DACO: 2.11.2,2.11.3 CBI
1904458	2010, Cover Letter - Response to Clarification Request, DACO: 0.8, 2.11.2, 2.13.1, 2.13.3, 2.13.4
1904459	2010, Supplemental Data to Eurofins/PSL Study 19915: Arsenic Analysis, DACO: 2.13.4 CBI
1937277	2010, Cover Letter – Response to Clarification,
1937278	2010, Basic Copper Carbonate: Preliminary Analysis, DACO: 2.13,2.13.1,2.13.2,2.13.3 CBI
1948280	2010, Basic Copper Carbonate: Description Of Starting Materials, DACO: 2.11.2 CBI

2.0 Human and Animal Health

1676681	2003, Acute Oral Toxicity Study in Rats - Defined LD50, DACO: 4.2.1
1676682	2003, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.2.2
1676683	2008, Acute Inhalation Toxicity Study in Rats, DACO: 4.2.3
1676684	2003, Primary Eye Irritation Study in Rabbits, DACO: 4.2.4
1676685	2003, Primary Skin Irritation Study in Rabbits, DACO: 4.2.5
1676686	2008, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.2.6
1730512	2005, Acute Oral Toxicity: Up-And-Down Procedure in Rats, DACO: 4.6.1
1730513	2005, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2

1730514 2005, Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.6.3
1730515 2005, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
1730516 2005, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
1730517 2005, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6

3.0 Value

PMRA Document Number	Reference
1730531	Freeman, Mike H.; McIntyre, Craig R., 2008, A Comprehensive Review of Copper-Based Wood Preservatives with a focus on new micronized or dispersed copper systems, Forest Products Journal 58(11): 6-27. DACO: 10.2.1,10.2.3.1,10.2.3.2,10.2.3.3
1730536	2009, Efficacy Laboratory Trails, DACO: 10.2.3.2
1750644	2007, Laboratory determination of the fungicidal effectiveness of a novel copper-based preservative system, DACO: 10.2.3.2(G)
1750646	2007, Evaluation of a Micronized Copper-QUAT Wood Preservative Formulation by AWPA E7 Field Stake Testing, DACO: 10.2.3.2(G)
1750649	2008, Summary of Average Decay Ratings in Soil Bed Condition, DACO: 10.2.3.2(G)
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1730537	2009, Efficacy: Small scale Trials, DACO: 10.2.3.3
1730538	2009, Efficacy Operation Field Trials, DACO: 10.2.3.4
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1749921	2008, Treatability of Second Growth Hem-fir with Alternative and Emerging Preservatives, DACO: 10.2.3.4
1730539	2009, 10.3.2 Non-safety Adverse Effects, DACO: 10.3.1,10.3.2
1730540	2005, Evaluation of the corrosion characteristics of common steel nails in contact with smart sense treated wood, DACO: 10.3.2
1730541	2008, Evaluation of the corrosion characteristics of aluminum when in contact with MicroPro treated wood, DACO: 10.3.2

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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2.0 Environment

PMRA # 1719804. 2009. Proposed Re-evaluation Decision – PRVD2009-04: Copper Pesticides. PMRA H113-9/2005. 91pp.